Erythropoetine effects on cycling performance.

Gepubliceerd: 13-01-2016 Laatst bijgewerkt: 13-12-2022

Treatment with rhEPO has no effects on performance parameters measures by exercise tests.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21046

Bron
NTR

Verkorte titel
N/A

Aandoening

Cycling (wielrennen), endurance performance (uithoudingsvermogen)

Ondersteuning

Primaire sponsor: Internal (Centre for Human Drug Research)
Overige ondersteuning: Internal (Centre for Human Drug Research)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Exercise tests
All subjects will breathe during the exercise test through a facemask that will be connected to an oxymeter to collect inspired and
expired gasses for analyzing:

- Oxygen consumption, VO2 (L/min)
- Carbon dioxide production, VCO2 (L/min)
- Respiratory minute ventilation, VE (L/min)
- Tidal volume, Vt (L)
- Respiratory frequency, Rf
- Maximal oxygen consumption, VO2,max (ml kg-1 min-1)
During the exercise tests blood will be collected at predetermined stages to measure:
- Lactate levels
- Tissue plasminogen activator
- Creatinine phosphokinase
- C-reactive protein levels
VO2 and VCO2 will be used to calculate:
- Ventilatory equivalent for oxygen (VE/VO2), eqVO2
- Ventilatory equivalent for carbon dioxide (VE/VCO2), eqVCO2
these values will be used to determine:
- Ventilatory threshold 1, VT1
- Ventilatory threshold 2, VT2
Physiological parameters that will be determined at VT1 and VT2:
- Oxygen consumption, VO2 (L/min)
- Oxygen consumption per kg, VO2 (L/min/kg)
- Percentage of maximal oxygen consumption, %VO2max (L/min)
- Power output, P (J/s)
- Power output per kg, P (J/s/kg)
Physiological parameters that will be determined at maximal effort:
- Maximal oxygen consumption, VO2max (L/min)
- Maximal oxygen consumption per kg, VO2max (L/min/kg)
- Maximal power output, Pmax (J/s)
- Maximal power output per kg, Pmax (J/s/kg)
- Lactate values
Other determinations:
- Lactate threshold 1, LT1
- Lactate threshold 2, LT2
- Cycling economy, CE (W L-1 min-1)
- Gross efficiency, GE (%)
- Heart rate (bpm)
- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)
Competition
Maximal and submaximal exercise parameters that will be measured and calculated during the competition:
- Power (W)
- Heart rate (bpm)
- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)

Toelichting onderzoek

Achtergrond van het onderzoek

Subjects will be recruited in The Netherlands.

Doel van het onderzoek

Treatment with rhEPO has no effects on performance parameters measures by exercise tests.

Onderzoeksopzet

Efficacy and Biological Passport: Every two weeks

Safety: Continuously and every week at dosing, every 2 weeks at exercise tests.

Doping: at several timepoints

Onderzoeksproduct en/of interventie

Weekly subcutaneous doses of Neorecormon (5000 IU, or adjusted to reach the desired Hemoglobin increase, maximum dose is 10.000 IU). Additionally, all subject will receive Vitamin C supplementation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Well-trained (as determined by cycling history and maximal power output >4 W/kg) male subjects, 18 to 45 years old (inclusive)

2. Subjects must be healthy / medically stable on the basis of clinical laboratory tests, medical history, vital signs, and 12-lead ECG performed at screening, including exercise ECG.

3. Each subject must sign an informed consent form

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any clinically significant abnormality, as determined by medical history taking and physical examinations, obtained during the screening visit that in the opinion of the investigator would interfere with the study objectives or compromise subject safety.

2. Unacceptable known concomitant diagnoses or diseases at baseline, e.g., known cardiovascular, pulmonary, muscle, metabolic or haematological disease, renal or liver dysfunction, ECG or laboratory abnormalities, etc.

3. Unacceptable concomitant medications at baseline, e.g., drugs known or likely to interact with the study drugs or study assessments.

4. Unacceptable potential cycling performance enhancing medications at baseline, e.g. Erythropoiesis-stimulating agents, Anabolic Androgenic Steroids, Growth Hormone, Insulin, IGF-I and Beta-Adrenergic Agents or methods, e.g. altitude tents.

5. Blood transfusion in the past three months.

6. Loss or donation of blood over 500 mL within three months.

7. Participation in a clinical trial within 90 days of screening or more than 4 times in the

previous year.

8. Known hypersensitivity to the treatment or drugs of the same class, or any of their excipients.

9. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or
interpretation of the results such as drug or alcohol dependence or psychiatric disease.

10. Positive urine drug test at screening, during visits at the clinical research unit and during the competition.

11. Positive alcohol breath test at screening, during visits at the clinical research unit and during the competition.

12. Haemoglobin (Hb) concentration > 9.8 mmol/l at screening.

13. Hb concentration < 8 mmol/l at screening.

14. Haematocrit (Ht) ≥ 48% at screening.

15. Ferritin < 80 ng/mL

16. Being subject to WADA's anti-doping rules, meaning being a member of an official cycling union or other sports union for competition (such as the KNWU) or participating in official competition during the study.

17. Positive results from serology at screening (except for vaccinated subjects or subjects with past but resolved hepatitis)

18. Previous history of fainting, collapse, syncope, orthostatic hypotension, or vasovagal reactions.

19. Any circumstances or conditions, which, in the opinion of the investigator, may affect full participation in the study or compliance with the protocol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-01-2016
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5516
NTR-old	NTR5643
Ander register	: CHDR1514

Resultaten